K090311

MAY - 5 2009

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides details to understand the basis for a determination of substantial equivalence.

Submitter name, address, contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
317-521-3208

Contact Person: Kelly French

Date Prepared: February 2, 2009

Device Name

Proprietary name: Elecsys Rubella IgG CalCheck

Common name: Rubella IgG CalCheck

Classification name: Single (specified) analyte controls (assayed and unassayed)

Device Description

The Elecsys Rubella IgG CalCheck is a lyophilized product consisting of human anti-Rubella IgG antibodies in human serum matrix. During manufacture, the analyte is spiked into the matrix at the desired concentration levels.

Intended use

The Elecsys Rubella IgG CalCheck is an assayed calibrator control intended for use in the verification of the calibration established by the Elecsys Rubella IgG reagent on the Elecsys 2010, the MODULAR ANALYTICS E170, and **cobas e** immunoassay analyzers.

Comparison Table

The table below compares Elecsys Rubella IgG CalCheck with the predicate device, Elecsys C-Peptide Calcheck (K040157).

Characteristic	Elecsys C-Peptide CalCheck (K040157)	Elecsys Rubella IgG CalCheck
Intended Use	For use in the verification of the	For use in the verification of the calibration established

Characteristic	Elecsys C-Peptide CalCheck (K040157)	Elecsys Rubella IgG CalCheck
	calibration established by the Elecsys C-Peptide reagent on the Elecsys and cobas e immunoassay analyzers.	by the Elecsys Rubella IgG reagent on the Elecsys 2010, the MODULAR ANALYTICS E170, and **cobas e** immunoassay analyzers.
Levels	Three	Same
Format	Lyophilized	Same
Handling	Reconstitute with exactly 1.0 mL distilled or deionized water and allow standing closed for 15 minutes, then mix gently.	Same
Stability	Unopened: Store at 2-8°C until expiration date Reconstituted: 20 - 25°C: 4 hrs	Same
Matrix	Equine serum matrix	Human Serum

Performance Characteristics

The Elecsys Rubella IgG CalCheck was evaluated for value assignment and stability.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY - 5 2009

Kelly French
Regulatory Affairs Consultant
Roche Diagnostics
Roche Professional Diagnostics
9115 Hague Road
PO Box 50416
Indianapolis, IN, 46250-3831

Re: K090311

Trade/Device Name:	Elecsys Rubella IgG CalCheck
Regulation Number:	21CFR §866.1660
	21CFR §866.3510
Regulation Name:	Quality control material (assayed and unassayed)
	Rubella virus serological reagents
Regulatory Class:	Class I reserved (quality control)
	Class II (Rubella IgG)
Product Code:	JJX
	LFX
Dated:	February 5, 2009
Received:	February 6, 2009

Dear Ms. French:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at 240-276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K090311

Device Name: Elecsys Rubella IgG CalCheck

Indication For Use: The Elecsys Rubella IgG CalCheck is an assayed calibrator control intended for use in the verification of the calibration established by the Elecsys Rubella IgG reagent on the Elecsys 2010, MODULAR ANALYTICS E170 and **cobas e** immunoassay analyzers.

Prescription Use __X____ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Uwe Scherf

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K090311